

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Supplementary Examinations  
December 2022**

**Pharmaceutical Quality Assurance**

**(2017 Scheme)**

**Time: 3 Hours**

**Max. Marks: 75**

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw diagrams wherever necessary*

**Essays**

**(2x10=20)**

1. Discuss the quality control test for containers and rubber closures used in pharmaceutical industry.
2. Explain on selection, purchase, and maintenance of equipment.

**Short Notes**

**(7x5=35)**

3. Discuss in detail about ICH stability testing guidelines.
4. Explain the qualification and responsibility of personnel
5. Design the layout of premises with reference to tablet section.
6. Give a note on Master formula record.
7. Explain in detail about material management in good warehouse practice
8. Explain the protocol for conduct of a nonclinical laboratory study
9. What are the qualifications of UV-Visible spectrophotometer.

**Answer Briefly**

**(10x2=20)**

10. Explain the principle involved in NABL accreditation.
11. What are the elements of Quality by Design program.
12. Give the importance of GLP adopted in testing facilities operation.
13. Define quality audit.
14. How will you dispose the waste materials from laboratory.
15. Give any two purchase specifications of raw materials.
16. Differentiate between qualification and validation.
17. Explain the purpose of ICH guidelines.
18. Brief the disqualification of testing facilities.
19. Explain the general principles of calibration.

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